Significant Analysis for Rule Concerning Handling of Human Remains, New Chapter 246-500 WAC

Briefly describe the proposed rule.

This proposed rule revision would:

- Revise rules of the State Board of Health (SBOH) for human remains handling to reflect changes in law made by SSB 5752 in 2005, especially RCW 18.39.215.
- Move human remains handling provisions in chapter 246-490 WAC, Vital Statistics, to a new chapter 246-500 WAC, Handling of Human Remains.
- Change rule provisions to better reflect the religious diversity of the population of Washington and provisions of the State Constitution, Article 1, Section 11, Religious Freedom.
- Establish provisions to implement the waiver clause in RCW 18.39.215. Funeral directors or embalmers may delay placing under, or removing from, refrigeration unembalmed human remains for a maximum of 24 hours for specified activities, unless directed otherwise by a local health officer or medical examiner.
- Provide local health officers with authority to impose additional requirements or suspend requirements of this chapter to protect public health in emergency situations.
- Update the rule language to improve clarity.

Is a Significant Analysis required for this rule?

Yes. Portions of this rule require a significant analysis. However, the SBOH has determined that no significant analysis is required for the following portions of the rule:

- 246-500-010, except subsection (13) defining "refrigerate," adds clarity without imposing additional requirements beyond existing provisions in WAC 246-490-040.
- 246-500-020, except subsection (1), adds clarity without imposing additional requirements beyond existing provisions in WAC 246-490-040.
- 246-500-030(1), specifying that funeral directors and embalmers must refrigerate or embalm human remains upon receipt, is explicitly required by RCW 18.39.215. The requirement that others assisting in preparation of human remains do the same as funeral directors and embalmers is an existing provision in WAC 246-490-040(3).
- 246-500-040, except subsection (2)(a), adds clarity without imposing additional requirements beyond existing provisions in WAC 246-490-050 or explicitly provided by law under RCW 70.58.230.

• 246-500-050 adds clarity without imposing additional requirements beyond existing provisions in WAC 246-490-060 or explicitly provided for by law under RCW 68.50.230.

The remainder of this document will focus on those portions of the rule that do require a significant analysis.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

- RCW 43.20.050(2)(e) authorizes the SBOH to adopt rules to prevent and control diseases including rules regarding the handling of remains of deceased persons.
- In 2005, SSB 5752 changed RCW 18.39.215 to require funeral directors and embalmers to refrigerate or embalm human remains upon receipt, rather than within 24 hours. This law provides that a proper state or local authority may provide a written waiver for these provisions for a specified period of time.
- The Washington State Constitution, Article 1, Section 11, declares that freedom of conscience in all matters of religious belief shall be guaranteed to every individual, except to justify acts inconsistent with the peace and safety of the state.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

These proposed rule revisions are needed to meet the goals of the laws mentioned above.

• Update the rules of the SBOH for human remains handling to reflect changes in law made by SSB 5752, especially RCW 18.39.215. The SBOH has adopted rules for the handling of human remains in chapter 246-490 WAC. The provisions of these rules include requirements for funeral directors and embalmers to refrigerate or embalm human remains within 24 hours after receipt and once refrigerated not remove from refrigeration. When these provisions where adopted, they were compatible with RCW 18.39.215. However, SSB 5752 changed RCW 18.39.215 to require funeral directors and embalmers to refrigerate or embalm human remains upon receipt, rather than within 24 hours. RCW 18.39.215 also allows for a proper state authority to provide a written waiver to these refrigeration requirements for a specified period of time. The SBOH is a proper state authority under RCW 43.20.050(2)(e) to develop rules on human remains handling and, therefore, provide such a waiver. The waiver proposed by this rule would allow for removal of human remains from refrigeration for necessary activities to be carried out for final disposition of the remains, viewing for identification of the deceased, and for practices that are part of cultural and religious beliefs for preparing human remains for final disposition and honoring the deceased. The waiver criteria proposed would better reflect the religious diversity of the

population of Washington and provisions of the State Constitution, Article 1, Section 11, Religious Freedom.

- The proposed rule revision would reorganize the SBOH rules on human remains handling to make them easier for the regulated community and the public to find. Provisions in chapter 246-490 WAC, Vital Statistics, would be moved to a new chapter 246-500 WAC, Handling of Human Remains. Rules are needed to control the handling of human remains to prevent the spread of infectious disease to the community. The proposal contains updates to rule language to improve clarity, allow more flexibility, and provide greater respect for religious beliefs.
- The rule proposal would give local health officers authority to impose additional requirements or suspend requirements of this chapter to protect public health in emergency situations. Local health officers need to be able to make professional decisions necessary to protect the health of their community from the spread of infectious disease. It is especially important for local health officers to have this specific authority to allow them to develop flexible plans to respond to threats such as pandemic influenza.

No alternative for rulemaking was identified. However, some alternatives to certain provisions of the proposal were identified. These are described in D below.

The consequences of not adopting this rule revision are that funeral directors will be prevented from delaying or removing unembalmed human remains from refrigeration for necessary practices that are part of final disposition, to allow for identification of the deceased, or to allow for cultural and religious practices to prepare and honor the diseased. Another consequence of not adopting the rule revision would be to leave the authority of local health officers unclear regarding determining handling of human remains during disasters and other emergencies.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The portions of the rule that are significant are analyzed in the numbered list below. As discussed above, other portions of the rule are not significant and are therefore not included in this analysis.

1. 246-500-010(13) defines "refrigerate."

Description: This subsection defines "refrigerate" to mean placing in a mechanically cooled unit maintained at a maximum temperature of 48 degrees Fahrenheit in a funeral establishment or elsewhere. It also means packing a body with dry ice to cool it.

Analysis: Existing requirements in WAC 246-490-040 for funeral directors, embalmers, or others assisting in preparation to refrigerate unembalmed human remains within 24 hours of receipt do not specify the meaning of refrigerate. However, licensing requirements for funeral directors and embalmers in WAC 308-48-031 require funeral establishments to have mechanical refrigeration at a maximum temperature of 48 degrees Fahrenheit. The definition of refrigerate proposed in WAC 246-500-010(13) would clarify that the term has the same meaning within a funeral establishment as used in WAC 308-48-031. However, the proposed rule provides two options for cooling for locations outside of funeral establishments: (1) mechanical refrigeration at 48 degrees Fahrenheit or (2) packing the human remains in dry ice. Packing dry ice around a body provides a means to cool it that could help slow decomposition and, therefore, the release of body fluids. Dry ice could provide a cooling method when mechanical refrigeration is not available, such as at a temporary holding facility. Dry ice does not melt to water, which would present a disposal problem. However, it releases carbon dioxide gas and would not be suitable for use in a poorly ventilated space. This provision provides more flexibility for cooling human remains where mechanical refrigeration is less practical than in a funeral establishment. It would impose no new costs on the regulated community.

2. 246-500-020(1) adds embalmers and others directly handling or touching human remains to those listed as being required to take specified precautions.

Description: This subsection would add embalmers and others to persons listed in existing WAC 246-490-040(2) who must (a) wash their hands and other exposed skin surfaces after contact with human remains, blood, or body fluids; (b) use barrier precautions (such as plastic gloves) if a procedure involves potential contact with blood, body fluids, or internal tissues; and (c) not eat, drink, or smoke in areas where handling human remains or body fluids takes place.

Analysis: These provisions are not more restrictive than existing requirements for preventing occupational exposure to bloodborne pathogens under chapter 296-823 WAC of the Department of Labor and Industries. However, this rule would extend the requirements beyond occupational settings to anyone handling or touching human remains. It would include persons handling a body after a disaster or during preparation of the body according to a cultural or religious practice. Human remains present a potential risk for transmission of certain infectious diseases immediately upon death and for up to several weeks after death. Persons could be exposed to infectious agents surviving in the human remains through blood, body fluids, and internal tissues uncovered by injury or autopsy. Barrier precautions are appropriate to minimize such exposure and to prevent potential disease transmission to the community. Exposure to intact skin of a deceased person presents a low risk for disease transmission. For such situations, only moderate precautions of washing hands and not engaging in hand-to-mouth activities around the deceased are appropriate precautions to minimize disease transmission. The SBOH considers the health protection provided by these provisions to

outweigh the potential minimal cost of barrier precautions such as disposable gloves (less than one dollar per pair).

3. 246-500-030(2) provides for delay or removal of unembalmed human remains from refrigeration for specified activities for a specified maximum time.

Description: This subsection would provide a waiver to RCW 18.39.215, a law which requires funeral directors and embalmers to refrigerate or embalm human remains immediately upon receipt. The waiver would allow funeral directors, embalmers, and others assisting in the preparation of human remains for final disposition to delay or remove unembalmed remains from refrigeration for specified activities: (a) embalming; (b) transporting; (c) cremating or burying; (d) viewing for identification purposes for a maximum of one hour; or (e) activities commonly part of religious and cultural practices carried out by family or persons especially knowledgeable about the practices for a maximum of 24 hours.

Analysis: The provisions of existing WAC 246-490-040(3) require funeral directors, embalmers and others assisting in the preparation of human remains to embalm or refrigerate the remains within 24 hours of receipt and once refrigerated not remove the remains from refrigeration. In 2005, SSB 5752 changed RCW 18.39.215 to require funeral directors and embalmers to embalm or refrigerate human remains upon receipt. However, this law provides that a proper state or local authority may provide a written waiver for these provisions for a specified period of time. The SBOH is designated authority by RCW 43.20.050(2)(e) to adopt rules to prevent and control diseases including rules regarding the handling of remains of deceased persons. The Washington State Constitution, Article 1, Section 11, declares that freedom of conscience in all matters of religious belief shall be guaranteed to every individual, except to justify acts inconsistent with the peace and safety of the state.

This proposal would allow funeral directors and embalmers to delay or remove unembalmed human remains from refrigeration for activities necessary for final disposition: transporting, cremating, or burying. It would allow removal from refrigeration for viewing necessary for identification purposes for a short period of time (one hour maximum). Viewing of the deceased person to confirm his/her identity is a necessary activity for a close relative or friend. Without this provision, an unembalmed body could not be viewed for identification after receipt at a funeral establishment.

This proposal also would allow funeral directors, embalmers, and others assisting in preparation to delay or remove unembalmed human remains from refrigeration for common cultural and religious practices for a maximum of 24 hours. These practices include washing, anointing, praying over, reading to, singing to, sitting with, guarding, viewing, or otherwise accompanying the deceased. Many people hold these practices to be an integral part of their religious beliefs for preparing the deceased. They hold that the practices must be performed by family or others who have the same religious beliefs, not by funeral establishment employees. They also hold that embalming is not acceptable to their religious beliefs. Without this provision, many individuals in Washington would

have their religious beliefs restricted without there being a significant threat to the health of the community.

The existing WAC 246-490-040(3) allowed a maximum of 24 hours for such practices without reports of adverse impacts to the health of the public. However, unembalmed, unrefrigerated human remains will begin to show significant decomposition and release of body fluids after 24 hours. Therefore, this rule limits the waiver from refrigeration for unembalmed human remains to a maximum of 24 hours unless a local health officer allows otherwise after evaluating specific circumstances, the need to protect public health, and religious beliefs of the deceased.

Unembalmed, unrefrigerated human remains will begin to decompose and release body fluids. Skin structure will deteriorate; the abdomen will become distended; urine and feces will be released; and air can be released from the lungs. Bodily wastes could contain enteric pathogens such as hepatitis A virus, Salmonella, or Shigella. Blood could contain hepatitis B virus, hepatitis C virus, or human immunodeficiency virus (HIV). Droplets released from the lungs could contain tuberculosis bacilli. Body fluids could contain other significant pathogens that are rare such as the meningococcus or methicillin resistant Staphylococcus aureus (MRSA). Although clean, intact skin is not a mode of transmission of these agents, body fluids could be. Therefore, this rule contains a provision that persons helping to prepare human remains must use appropriate barrier precautions (e.g., plastic gloves) when their activities involve potential contact with body fluids. It should be noted that the use of barrier precautions would not be required by this rule for persons contacting only intact skin of a deceased person that is not soiled with blood or body fluids. The SBOH considers the health protection provided by these provisions to outweigh the potential minimal cost of barrier precautions such as disposable gloves (less than one dollar per pair).

4. 246-500-030(3) provides for a restriction to delay or remove unembalmed human remains from refrigeration if an immediate threat to human health might occur.

Description: This subsection would provide authority for a local health officer or medical examiner to require a funeral director, embalmer, or other person assisting in the preparation of human remains to prohibit activities otherwise allowed by subsection (2)(e) if those activities would pose a direct threat to human health.

Analysis: This provision would allow a local health officer to restrict handling of unembalmed, unrefrigerated human remains in a funeral establishment to protect public health. Such authority could help protect the health of the community when a person has died from a highly infectious disease with a high death rate (e.g., MRSA, viral hemorrhagic fever, or rabies). The SBOH considers this an important authority to provide local health officers and medical examiners to protect the community from severe, but rare, emerging disease agents. The SBOH considers this to be consistent with constitutional provisions of Article 1, Section 11, in that religious practices may be restricted, to a minimal degree, for the safety of the community.

5. 246-500-040(2)(a) requires the use of double leak-resistant containers for the shipment of human remains by common carrier.

Description: This subsection would simplify requirements for packing human remains for transportation by common carrier. It would require packing the remains in a leak-resistant container placed inside another leak-resistant container to prevent the release of body fluids.

Analysis: Existing provisions in WAC 246-490-050(2) require human remains prepared for shipment by common carrier to be enclosed in a casket or transfer case in a tightly closed outer box. However, family wishes do not always call for the use of a coffin. The existing rule does not describe what a transfer case must be. If transport by common carrier takes more than 24 hours, the existing rule requires the human remains to be embalmed or covered in material soaked in preservative, placed in a burial pouch, and then placed inside a heavy canvas rubberized pouch sealed along the zippered area with collodion. The requirements specified for unembalmed bodies for transport for more than 24 hours are largely ignored by the funeral industry because the materials called for are not readily available and are not always appropriate. Some people hold that requiring preservative-soaked materials be placed in contact with the deceased is against their religious beliefs. Preservative soaked wrappings would not prevent the decomposition of human remains, which mainly occurs from the inside out rather than the outside in.

Almost all human remains shipped by common carrier these days are sent by air. Airline company rules and international rules specify how human remains are to be packed for shipment. The international rules differ between countries. However, they all have the same goal of requiring packing to prevent leakage of body fluids. Body fluids from unembalmed human remains can present a potential health risk for disease transmission. Fluids from embalmed human remains can present a potential health risk from leakage of formalin solutions and variable inactivation of pathogenic organisms.

Proposed subsection WAC 246-500-040(2) would simplify the state requirements for packing human remains for shipment by common carrier. The proposal would require the person preparing the remains for shipment to place the remains in doubled leak-resistant containers. The types of containers required are not specified. Many different types are available and are regularly used by the industry today. This proposed rule would allow for more alternative methods of packing, which could better accommodate requirements of airlines and international rules. The combination of containers would be required to prevent the release of body fluids. The requirements would be applicable for packing both embalmed and unembalmed human remains. The simplified requirements proposed by this subsection would add no costs above those for existing requirements for preparing human remains for shipment by common carrier.

6. 246-500-060 provides local health officers with authority to impose additional requirements or suspend any requirements of this chapter in emergency situations.

Description: This section would provide specific authority for local health officers to make decisions involving human remains handling that are appropriate for responding to emergency situations in their jurisdictions. It would allow local health officers to impose additional requirements for handling human remains, such as to control a major disease outbreak. It would also give local health officers authority to suspend requirements of this chapter is such emergency situations, such as to allow storage of human remains in an unrefrigerated building after a major disaster.

Analysis: The local health officer is provided authority under RCW 70.05.070(2) to "take such action as is necessary to maintain health and sanitation...control and prevent the spread of any dangerous, contagious or infectious diseases..." The proposed WAC 246-500-060 clarifies that this authority of local health officers to make professional decisions necessary to protect the health of the community specifically applies to SBOH rules for human remains handling during emergency situations. The SBOH considers the public health benefit of this provision for emergency situations (e.g., pandemic influenza) outweighs any potential cost.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

SBOH staff worked closely with constituents and the public to minimize the burden of this rule. For example, staff contacted funeral directors and representatives of various religions (e.g., Jewish and Washat). In the course of these and other efforts, the following alternative version(s) of the rule were rejected:

Alternative version #1: SBOH considered providing in the rule proposal an allowance to delay or remove unembalmed human remains from refrigeration for up to 72 hours for religious practices [WAC 246-500-030(2)]. However, time beyond 24 hours poses an increased risk for release of body fluids from human remains due to advancing decomposition. Funeral directors objected to 72 hours, and any time beyond 24 hours, because of the potential increased risk of exposure to them, their staff, and visitors in funeral establishments. Also, the Department of Licensing advised Board staff that their code of practice for funeral directors and embalmers would prohibit those professions from restricting practices allowed under law or rule. This would have placed the funeral directors in a position of having limited discretion in controlling the handling of unrefrigerated human remains that were decomposing very rapidly in the funeral establishment. Elders of the Yakama Nation, knowledgeable about the Washat religion, advised Board staff that 24 hours was sufficient time to have unembalmed human remains out of refrigeration for religious preparations in a funeral establishment, although more time would provide for more flexibility in situations such as for a death immediately before the Sabbath day. Jewish and Muslim religious beliefs hold that final disposition of the deceased must be completed in one day.

The alternative proposal chosen is to allow a maximum of 24 hours for delay or removal from refrigeration for unembalmed human remains. This would allow for a situation where death occurred on Saturday afternoon, the body is refrigerated upon receipt by the funeral director, removed from refrigeration for religious practices on Monday and for a maximum of 24 hours afterwards in the funeral establishment. Compared to the alternative of 72 hours, the proposed rule is less burdensome for funeral directors.

Alternative version #2: SBOH staff considered retaining in the proposed rule [WAC 246-500-040(2)] the provisions for wrapping unembalmed human remains in preservative-soaked absorbent material for shipment by common carrier, which is contained in the existing rule [WAC 246-490-050(2)]. However, SBOH staff was advised by a Rabbi and a representative of the Seattle Jewish Chapel that wrapping the deceased in preservative-soaked materials is contrary to Jewish religious beliefs. Also, staff of the Department of Licensing informed SBOH staff that the requirement in the existing rule was outdated and ignored by funeral directors because the materials that are called for are not readily available and would be cumbersome to use.

The alternative proposal chosen is to simplify the requirements for packing to require the use of doubled leak-resistant containers. Compared to the alternative version in existing rule, the proposed rule is less burdensome for funeral directors and does not infringe on religious beliefs.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom this rule applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not knowingly conflict with any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

Yes, the rule is coordinated to the maximum extent practicable with other applicable laws, including chapters 68.04, 68.50, 18.39, and 70.58 RCW. Board staff coordinated development of this rule proposal with staff of the Department of Licensing, Funeral and Cemetery Program.